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EXAMINER

SCHMIDTMANN, BAHAR

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,158	Applicant(s) RATNAM ET AL.	
	Examiner BAHAR SCHMIDTMANN	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-52, 54, 55 and 59 is/are pending in the application.
- 4a) Of the above claim(s) 26-47, 54 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-52 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/23/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's Amendment and Remarks filed on 16 November 2010 in which claims 53 and 56-58 were canceled, claims 48-52 were amended to change the scope and breadth of the claims, and claim 59 was newly added.

Claims 26-52, 54, 55 and 59 are pending in the current application. Claims 26-47, 54 and 55 remain withdrawn as being drawn to a non-elected invention. Claims 48-52 and 59 are examined on the merits herein.

WITHDRAWN REJECTIONS

Applicant's amendment, filed 16 November 2010, with respect to the rejection of claims 48-53, 57 and 58 under 35 U.S.C. § 112, first paragraph, for scope of enablement, has been fully considered and is persuasive. Claims 53, 57 and 58 have been canceled. Claims 48-52 and 59 have been amended to incorporate the sucralose into the independent claims. However, the sucralose as currently recited does preclude additional ingredients or elements from being present in the mixture. Thus, direct drying by means such as conventional spray drying is enabled since this is a known method for obtaining sucralose containing compositions.

The rejection is hereby **withdrawn**.

MODIFIED REJECTIONS

The following are new ground(s) or modified rejections necessitated by Applicant's amendment, filed on 16 November 2010, where the limitations in pending claims 48-52 as amended now have been changed, and claim 59 was newly added. Specifically, the newly added limitation "free-flowing" requires a modification of the 103 rejection, as well the deletion of the recitation "directly from a process of crystallization". Therefore, rejections from the previous Office Action, dated 16 July 2010, have been modified and are listed below.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 47-52 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "The 1',6' Dichloro-1',6'-Dideoxy- β -D-Fructo-Furanosyl-4-Chloro-4-Deoxy- α -D-Galactopyranoside, its intermediates, its derivatives" in claims 48, 50-52 render the claims and dependent claims 49 and 59 herein indefinite. It is unclear what intermediates or derivatives are encompassed herein, and/or what these chemical structures would be.

The Merriam-Webster's Online Dictionary defines "derivative" as "a chemical substance related structurally to another substance and theoretically derivable from it" (cited in previous Office Action).

Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "its intermediates, its derivatives herein. One of ordinary skill in the art would clearly recognize that a "derivative of sucralose" would read on those compounds having any widely varying groups that could be used to substitute the compound. Any significant structural variation to a compound would be reasonably expected to alter its properties; e.g. physical, chemical, physiological effects and functions.

The only chlorinated "sucrose" compounds described are sucralose-6-acetate and its deacylated form, presumably sucralose (p.21 appears to incorrectly recite the chemical names of the compounds produced, lines 16-20, compare with drawing figure 1 and instant claims).

Response to Arguments

Applicant's arguments with respect to claims 49-52 and 59 have been considered but are moot in view of the modified ground(s) of rejection, necessitated by Applicant's amendment.

The rejection is hereby **maintained**.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48-52 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Song et al. (US Patent No. 5,227,182, cited in previous Office Action).

Song et al. discloses a solid powder form of sucralose (1',6'-dichloro-1'6'-dideoxy- β -D-Fructo-Furanosyl-4-Chloro-4-Deoxy- α -D-Galactopyranoside) that is agglomerated (broadly and reasonably interpreted as non-crystalline), (column 4, lines 66-68 to column 5, lines 1-5). Song et al. discloses a solid form can then be ground to a specific particle size (column 5, lines 50-54). Song et al. discloses sucralose can be dried and added to chewing gum (claims 1, 7 and 18). Song et al. discloses sucralose can be spray-dried (broadly and reasonably interpreted as direct drying), wherein the sucralose is mixed with maltodextrin (figure 3). Song et al. discloses the sucralose in a free-flowing powder form, which is produced as a result of spray-drying (column 5, lines 50-54).

Song et al. does not expressly disclose the physical property limitations including average particle size (instant claims 49-52), moisture content (instant claim 49, 51), shape (instant claim 51). Because the Song et al. reference discloses directly drying a solution comprising sucralose, there is a reasonable expectation that the solid powdered form of sucralose inherently possesses the instantly claimed physical properties.

See MPEP 2113, for product-by-process claims: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability

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is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' solid free-flowing powder form of sucralose differs, and if so to what extent, from the solid free-flowing powder form of sucralose discussed in Song et al. Accordingly, it has been established that the prior art product, which are produced in a substantially similar manner as instantly claimed, demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed product and that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Furthermore, the Office is not equipped to conduct experimentation in order to determine whether or not the composition of Song et al. comprises each and every physical property recited in claims 48-52 and 59. Accordingly, it has been established that the prior art composition, which is made in the same manner as the instant composition and, according to Song et al., demonstrates a reasonable probability that it is either identical or sufficiently similar to the composition in claims 48-52 and 59 that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known compound is not disclosed in a reference does not make the known compound newly patentable. See MPEP 2112.

Thus, the disclosure of Song et al. anticipates claims 48-52 and 59 of the instant claims.

Response to Arguments

Applicant's arguments filed 16 November 2010 have been fully considered but they are not persuasive.

Applicant has argued that the Song reference teaches a mixture of sucralose and an agglomerating material, which is an external addition. Applicant contends that this is not "sucralose" itself nor a derivative or intermediate according to the instant subject matter. Applicant contends that the instantly claimed subject matter pertains to sucralose or their derivatives or intermediates and not their mixture with another chemical entity.

In reference to instant claim 49, there does not appear to be presently recited any transitional language that would limit the scope of the claims to only "sucralose, its derivatives or intermediates". The instant claims do not recite phrases such as "consisting of", which according to MPEP 2111.03 could limit the scope of the claims to exclude any element, step or ingredient not recited in the claims. Additionally, the compounds encompassed by "*derivatives or intermediates*" are not defined and could broadly and reasonably encompass a multitude of breakdown products of the sucralose itself. Finally, the only transitional phrase recited "at least a part of which is..." implies

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that there are other elements or ingredients mixed with the instantly claimed solid free-flowing powder form of sucralose not currently recited. Therefore, as currently recited, it is reasonable to interpret the claims as including additional elements, steps or ingredients not recited in the claims.

The rejection is hereby **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 48-52 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song et al. (cited in the previous Office Action) in view of Jackson et al. (European Patent Publication No. 255,260, cited in the previous

Office Action) and Kabbani et al. (US Patent No. 6,646,121, cited in the previous Office Action).

Song et al. teaches as discussed above.

Song et al. does not expressly disclose the physical property limitations including average particle size (instant claims 49-52 and 59), moisture content (instant claim 49, 51 and 59), shape (instant claim 51).

Jackson et al. teaches that sucralose has been solidified by freeze drying to obtain a solid powder form (p.1, second paragraph). Jackson et al. also teaches sucralose can be crystallized to obtain anhydrous products that are stable and inert (p.1, third paragraph). However, Jackson et al. teaches that the crystallized sucralose changes color relatively quickly under storage (p.1, third paragraph to p.2, first paragraph). Jackson et al. teaches that reducing the particle size and limiting the distribution to 5 to 10 microns for dry sucralose enhances the thermal stability of the compound (p.2, second paragraph).

Kabbani et al. teaches sucralose having a residual moisture content between about 0.5 to about 2% by weight (claim 3). Kabbani et al. teaches that dry product stability is proportional to residual moisture content (column 7, lines 48-51). Kabbani et al. teaches that moisture content exhibits the largest influence upon product stability (column 7, lines 48-51).

It would have been obvious at the time the invention was made to obtain a solid free-flowing powder form of sucralose having a particle size of between 5 to 10 microns and a residual moisture content between about 0.5 and to about 2% by weight.

Based on the teachings of the MPEP and KSR cited in the previous Office Action, by employing the rationale in (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention; one having ordinary skill in the art would have been motivated to obtain a solid powder form of sucralose having a particle size of between 5 to 10 microns and a residual moisture content between about 0.5 and to about 2% by weight. From Song et al. and Jackson, one having ordinary skill in the art would know that sucralose can be dried directly. Furthermore, one having ordinary skill in the art would know from the Jackson reference that the moisture content and size of the particles is extremely critical to the stability of the product and would be motivated to reduce the particle size to between 5 to 10 microns. And from the Kabbani et al. reference, one of ordinary skill in the art would specifically know that a residual moisture content of about 0.5 to about 2.0% by weight is also extremely critical to the stability of the sucralose compound. Therefore, it appears that in addition to the form of the product like a solid free-flowing powder form, which allows for easy manipulation into food products such as gum, one having ordinary skill in the art would be motivated to produce a sucralose having a specific particle size and moisture content in order to improve its long-term stability.

With respect to the particle size and residual moisture content recited in newly added claim 59, and the particle size of amended claim 51, it is noted that the ranges recited substantially overlap with that taught by Jackson and Kabbani. According to MPEP 2144.05, section I: "In the case where the claimed ranges "overlap or lie inside

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ranges disclosed by the prior art” a *prima facie* case of obviousness exists. In *re* Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In *re* Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)”.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teaching of the prior art.

Response to Arguments

Applicant's arguments filed 16 November 2010 have been fully considered but they are not persuasive.

In addition to arguments towards the Song reference, which have been discussed above, Applicant has argued that Jackson did not recognize direct drying to obtain an amorphous form of sucralose having a solid powder form with smaller particle size, low residual moisture content and stable form.

The instant claims are directed towards products, and their properties. How the products are made are not patentably distinguishable unless they provide products with different properties than that known in the prior art. It is not relevant if Jackson did not use the same method as applicant to arrive at the missing elements in the Song et al. reference of the claimed invention. Jackson did however recognize that sucralose is more stable at specific particle sizes and moisture content as instantly claimed. Therefore the instant claims directed towards sucralose with these properties is obvious over the prior art.

Applicant has also argued that Kabbani did not look towards the amorphous form of sucralose with a low residual moisture content as an alternative for crystalline sucralose.

One having ordinary skill in the art would have been motivated to improve the stability of sucralose since it allows for longer shelf life. The Kabbani reference, like Jackson, serves to demonstrate why one of ordinary skill in the art would have been motivated to have sucralose at the claimed properties, since it is only these properties that are missing from the Song et al. reference. One having ordinary skill in the art would have been motivated to modify the sucralose taught by Song et al. to ensure it has the particle size and moisture content at levels taught by the prior art, i.e. Kabbani and Jackson. Thus, the Kabbani and Jackson reference is applied in combination with Song et al. to show that the missing elements in Song et al. were in fact known in the art.

Finally, it should be noted that not all the claims require the sucralose to be amorphous. Specifically, claims 50, 51 and 52 do not require this limitation.

The rejection is hereby **maintained**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-52 and 59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 8 and 9 of copending Application No. 12/225378. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 2 of the '378 application is drawn to a solid amorphous sucralose having a particle size of about 3 microns. Claim 9 of the '378 application is drawn to a consumable composition containing the amorphous sucralose. Claim 1 of the '378 application is drawn to a crystalline sucralose having a particle size of about 5 microns, and claim 8 is drawn to a consumable product containing said crystalline sucralose.

The claims of the '378 application do not expressly disclose the moisture content of the compounds.

The specification of the '378 application teaches the moisture content of crystalline sucralose is 0.17% to 0.73% (p.27, table 1), 0.18% to 0.70% (p.27, table 2) and 0.20% to 1.10% (p.28, table 3). The specification of the '378 application teaches the moisture content of amorphous sucralose is about 0.05% (p.29, table 5).

Thus, the claimed invention is *prima facie* obvious over the '378 application.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments filed 16 November 2010 have been fully considered but they are not persuasive.

Applicant has requested that the provisional rejections be held in abeyance until patentable subject matter is identified. However, this request cannot be considered, especially in view that no patentable subject matter has yet been identified.

The obviousness double patenting rejections are hereby **maintained**.

Conclusion

In view of the rejections to the pending claims set forth above, no claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. BAHAR SCHMIDTMANN whose telephone number is 571-270-1326. The examiner can normally be reached on Mon-Thurs 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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